ANSI/ADA Specification No. 1
Reaffirmed by ANSI: June 2013

American National Standard/American Dental Association

Specification No. 1

Alloy for Dental Amalgam

Modified adoption of ISO 1559:1995, *Dental materials — Alloys for dental amalgam*

ADA American Dental Association®
Council on Scientific Affairs

2003

AMERICAN NATIONAL STANDARD/AMERICAN DENTAL ASSOCIATION SPECIFICATION NO. 1 FOR ALLOY FOR DENTAL AMALGAM

The Council on Scientific Affairs of the American Dental Association has approved revised American Dental Association Specification No. 1 for Alloy for Dental Amalgam. This and other specifications for dental materials, instruments and equipment are being formulated by working groups of the ADA Standards Committee on Dental Products (formerly Accredited Standards Committee MD156 for Dental Materials, Instruments and Equipment). The Committee has representation from all interests in the United States in the standardization of materials, instruments and equipment in dentistry. The Council has adopted the specifications, showing professional recognition of their usefulness in dentistry, and has forwarded them to the American National Standards Institute with a recommendation that the specifications be approved as American National Standards. The American National Standards Institute granted approval of ADA Specification No. 1 as an American National Standard on January 9, 2003. This standard becomes effective January 9, 2004.

The Council thanks the working group members and the organizations with which they were affiliated at the time the specification was developed:

Richard Mitchell (Chairman), University of Kentucky, Lexington, KY: Kamal Asgar, University of Michigan, Park Ridge, NJ; Robert Cooley, University of Texas, San Antonio, TX; John Engle, Oregon Health Sciences University, Portland, OR; Paul Hammesfahr, Dentsply Caulk, Milford, DE; Eugene Lautenschlager, Northwestern University, Chicago, IL; Frank Lentine, Lentine Enterprises, Ltd., Taylor, MI; David Mahler, Oregon Health Sciences University, Portland, OR; Miroslav Marek, Georgia Institute of Technology, Atlanta, GA; Spiro Megremis, American Dental Association, Chicago, IL; Ann-Marie Neme, University of Detroit Mercy, Detroit, MI; Toru Okabe, Baylor College of Dentistry, Dallas, TX; Howard Roberts, USAF Dental Investigations Service, Great Lakes, IL.

AMERICAN NATIONAL STANDARD/AMERICAN DENTAL ASSOCIATION SPECIFICATION NO. 1 FOR ALLOY FOR DENTAL AMALGAM

FOREWORD

(This foreword does not form a part of ANSI/ADA Specification No. 1, Alloy for Dental Amalgam).

This American National Standard was prepared under the supervision of the ADA Standards Committee on Dental Products. Specifically, Working Group 1.2 on alloys for amalgam and dental mercury of Subcommittee No. 1 Restorative Materials and Orthodontic Products, prepared this standard.

This third edition cancels and replaces Specification No. 1 (Revised November 1976; Addendum 1a approved November 1979; 1 and 1a reaffirmed 1995).

INTRODUCTION

This is a major revision of the Specification No. 1 published in 1976 and revised in 1979.

The language of this standard is very close to that of ISO 1559 **-** Alloys for dental amalgam (1994). There are, however, significant differences between this standard and ISO 1559. Compared with ISO 1559, this standard contains:

- No restrictions on the percentages of allowed elements;
- A smaller maximum creep value;
- A higher minimum one-hour compressive strength.

Note that this standard does not specify tests for bulk powder and powder that have been compacted into Tablets. Such tests might imply endorsement of filling of capsules with mercury and alloy in the dental office. This practice has been shown to increase the probability that there will be higher concentrations of mercury vapor in clinic air. At its October 1994 meeting, the American Dental Association House of Delegates passed a resolution recommending that dentists eliminate the use of bulk amalgam alloy and bulk mercury in their practices and that they use only capsulated alloy and mercury.

Important changes from the last edition of this standard include:

- Alloys can contain the noble metals and indium;
- Many of the tests now require a pass rate rather than an average value;
- The specimen for measuring dimensional change, requirements for the dimensional change testing device, and the range of allowable dimensional changes have been revised;
- A 24-hour compressive strength requirement has been added;
- A test for loss of mercury during amalgamation of capsules has been added;

- The precaution for zinc-containing alloys has been revised;
- The method for measuring foreign material has been revised;
- The manufacturer's instructions and outer package are required to list additional information about the alloy and mercury and about their safe handling;
- A wider range of temperatures for conducting the creep test is allowed.

Additional note to the Foreword for this Reaffirmation:

In 2012, the ADA Standards Committee on Dental Products approved a change in the terminology used for standards. ADA standards will no longer utilize the term Specification; standards will now be named as ADA Standards.

With this notice, this ADA Specification is now termed an ADA Standard. Where the term "specification" is used, it should be considered as "standard." It will be re-named as an ADA Standard in its next revision.

AMERICAN NATIONAL STANDARD/AMERICAN DENTAL ASSOCIATION SPECIFICATION NO. 1 FOR ALLOY FOR DENTAL AMALGAM

1 SCOPE

This specification is for alloys, composed mainly of silver, tin and/or copper, used in the preparation of dental amalgam. Only capsulated alloy is covered under this specification.

When a capsule containing mercury and alloy is shaken, the mercury and alloy react to form the metal-matrix composite called dental amalgam. Dental amalgam is designed for use in dentistry as a restorative material for decayed, fractured, or eroded teeth.

2 NORMATIVE REFERENCES

The following standards contain provisions, which, through reference in the text, constitute provisions of this American National Standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this American National Standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 78-4:1983, *Layouts for standards - Part 4: Standard for atomic absorption spectrometric analysis.*

ISO 286-2:1988, *ISO system of limits and fits - Part 2: Tables of standard tolerance grades and limit deviations for holes and shafts.*

ISO 468:1982, *Surface roughness — Parameters, their values and general rules for specifying requirements.*

ISO 1560: 1985, *Dental mercury.*

ISO 3310/1:1990, *Test sieves — Technical requirements and testing - Part 1: Test sieves of metal wire cloth.*

ISO TR 7405:1997, *Dentistry - Preclinical evaluation of biocompatibility of medical devices used in dentistry - Test methods for dental materials.*

ISO 7488:1991, *Electrically powered amalgamators.*

Elliott, I (Editor) Chemical Characterization. Institute of Metals. London 1988.

Beamish, Fred Earl. The analytical chemistry of the noble metals. Pergamon Press, Oxford, 1966.

3 DEFINITIONS

For the purposes of this American National Standard, the following definitions shall apply:

Alloy for dental amalgam: Alloy in fine particles, composed mainly of silver, tin, and copper, which, when mixed with mercury, produces a dental amalgam.